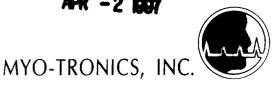
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1. Submitter's Information

Date of Submission:

January 10, 1997

Submitter's name and address:

Myo-tronics, Inc., 15425 - 53 Ave. So., Tukwila, WA 98188

Tel: (206) 243-4214

FAX: (206) 243-3625

Contact Name:

Mr. Fray Adib

2. Device Trade Name:

ESG-1 Electrosonogram or Sonograph

Common name:

Temporomandibular Joint Sound Recorder

Classification name:

Unclassified

- 3. Myo-tronics' ESG-1 Electrosonogram is substantially equivalent to: SONOPAK/QS manufactured by BioResearch of Milwaukee, Wisconsin.
- 4. Description of the device:

ESG-1 Electrosonogram is a non-invasive device that measures and records sounds emitted from the temporomandibular joint along with the relative position of the jaw as a means of assessing the status of the temporomandibular joint.

5. The ESG-1 Electrosonogram has the same technological characteristics as the above mentioned predicate device.